IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in Exhibit A
attached hereto

ORDER ADOPTING
MEMORANDUM OPINION AND ORDER
(*Daubert* ruling re: Steven MacLean, Ph.D.)

On April 12, 2017, plaintiffs filed a Notice of Adoption of Prior *Daubert* Motion of Steven MacLean, Ph.D. for Wave 4. [ECF No. 3625]. The court **ORDERS** that the Memorandum Opinion and Order (*Daubert* Motion re: Steven MacLean, Ph.D., P.E.) [ECF No. 2724] ("Prior Order") entered on September 2, 2016, as to the Ethicon Wave 1 cases is **ADOPTED** in the Wave 4 cases identified in Exhibit A.[1] The Prior Order is attached hereto as Exhibit B.

The court **DIRECTS** the Clerk to file a copy of this Order Adopting Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 4 cases identified in the Exhibit attached hereto.

ENTER: July 24, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

[1] On Exhibit A, I have marked through cases that are closed, on the inactive docket, not in Wave 4, could not be identified because of an error in the style or case number, or assigned to another District Judge.

EXHIBIT A

Plaintiff Name	Case No.
~~Baksic, Danielle and Brian~~	~~2:12-cv-03536~~
~~Beltran, Alba~~	~~2:12-cv-04824~~
~~Christopherson, Verla~~	~~2:12-cv-04365~~
~~Comstock, Margaret~~	~~2:12-cv-05345~~
~~Connolly, Peggy~~	~~2:12-cv-04026~~
~~Datz, Lillian~~	~~2:12-cv-03735~~
~~Fine, Vicki~~	~~2:12-cv-03167~~
Galarza, Delia	2:12-cv-03998
Geisinger, Melinda	2:12-cv-05112
~~Gracon, Pamela~~	~~2:12-cv-04516~~
~~Hahn, Kathleen~~	~~2:12-cv-04366~~
Humbert, Anne	2:12-cv-04170
~~Jucha, Anna~~	~~2:12-cv-03646~~
~~Kramer, Catherine~~	~~2:12-cv-03696~~
~~Lunsford, Sharon Kay~~	~~2:12-cv-03308~~
~~Mayes, Tammy~~	~~2:12-cv-03463~~
~~Neal, Glendora~~	~~2:12-cv-03615~~
Newton, Cynthia	2:12-cv-05517
~~Riffle, Kimberly~~	~~2:12-cv-03611~~
Robinson, Carol	2:12-cv-05573
~~Roman, Jeanette~~	~~2:12-cv-05255~~
~~Sheldon, Christine~~	~~2:12-cv-04508~~
~~Stensgard, Janet~~	~~2:12-cv-05389~~
~~Stepski, Zinaida~~	~~2:12-cv-05342~~
Thate, Connie	2:12-cv-04144
~~Towns, Bertha~~	~~2:12-cv-03306~~
~~Tucker, Diana~~	~~2:12-cv-04958~~
~~Wade, Mary~~	~~2:12-cv-04512~~

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Steven MacLean, Ph.D., P.E.)

Pending before the court is the Motion to Exclude, or in the Alternative, to Limit the Opinions and Testimony of Steven MacLean, Ph.D., P.E. [ECF No. 2205] filed by the plaintiffs. The Motion is ripe for consideration.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), among others.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.[1]

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations

[1] The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2205-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by

precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Steven MacLean, Ph.D., P.E., is a polymer scientist and engineer whom Ethicon offers as an expert witness. The plaintiffs challenge Dr. MacLean's testimony on a number of fronts.

First, the plaintiffs seek exclusion of Dr. MacLean's biocompatibility and regulatory opinions. In response, Ethicon states that Dr. MacLean "has not disclosed and will not offer opinions regarding biocompatibility or regulatory issues in this litigation." Resp. 5 [ECF No. 2287]. Accordingly, the plaintiffs' Motion on these issues is **DENIED as moot**.

Second, the plaintiffs challenge Dr. MacLean's reliance on Ethicon's seven-year dog study to opine that Prolene is not subject to degradation. Specifically, Dr. MacLean relies on the study's finding that Prolene does not lose molecular weight *in vivo*. The plaintiffs argue that this finding is unreliable because the study compared the molecular weight of the samples being studied to an inappropriate control (i.e., comparing Prolene 5/0 sutures to Prolene 4/0 sutures). Ethicon defends the study's findings and suggests plaintiffs' argument reflects a misunderstanding of the concept of molecular weight. During his deposition, Dr. MacLean explained that the molecular weight of the two versions of Prolene is the same because they are composed of the same base polymer, which he claims is the relevant comparison for molecular weight purposes. The court does not find that the plaintiffs' concerns with the dog study's findings render Dr. MacLean's testimony unreliable. The plaintiffs' Motion on this point is **DENIED**.

Third, the plaintiffs seek to exclude Dr. MacLean's testimony that Dr. Jordi's conclusions about the melting point of mesh are incorrect. To reach his conclusion, Dr. MacLean used several sets of data, including those of Dr. Jordi, from different studies to calculate molecular weight. The plaintiffs contend Dr. MacLean's

calculations involved unreliable extrapolations, and they take issue with both the combination of findings from different studies and the reliability of the studies themselves. The use of inputs from different studies does not necessarily render an expert's conclusions unreliable. However, the court is without sufficient information in this instance to explore the scientific validity of Dr. MacLean's assumptions and methods used in this instance. Accordingly, I **RESERVE** ruling on Dr. MacLean's calculations related to Dr. Jordi's testimony until the testimony can be evaluated firsthand at trial.

Fourth, the plaintiffs contend that Dr. MacLean is not qualified to offer pathology opinions because he is not a pathologist. However, as Ethicon points out, the opinions the plaintiffs characterize as pathology opinions are those related to staining, microtoming, and microscopy, which are processes used across medical and scientific fields, including polymer science. As an experienced polymer scientist and engineer, Dr. MacLean is qualified to opine on the chemical and physical interactions between fluid stains and polymer materials such as Prolene. Insofar as the plaintiffs challenge Dr. MacLean's qualifications, their Motion is **DENIED**.

Finally, the plaintiffs challenge the reliability of Dr. MacLean's experiment in which he used chemicals and ultra-violet radiation to intentionally degrade Prolene samples, sent the samples to a lab for Hematoxylin and Eosin (H&E) staining, and concluded the samples did not stain. Dr. MacLean uses these experiments to refute Dr. Iakovlev's opinions that H&E will stain the outer layer of degraded Prolene. The plaintiffs raise several arguments as to why Dr. MacLean's testing is unreliable.

Upon careful consideration of the plaintiffs' concerns, Ethicon's responses, and Dr. MacLean's expert report, I do not find that the challenges raised credibly undermine the reliability of Dr. MacLean's testing. Accordingly, the plaintiffs' Motion on this matter is **DENIED**.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the

perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this

type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **RESERVES in part**, and **GRANTS in part** the Motion to Exclude, or in the Alternative, to Limit the Opinions and Testimony of Steven MacLean, Ph.D., P.E. [ECF No. 2205].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: September 2, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE